

## **Exhibit C**

**EXHIBIT C:**  
**BMS PRODUCTS**

**I. ONCOLOGY PRODUCTS**

**Blenoxane**

Blenoxane (bleomycin sulfate) was approved on July 31, 1973. Blenoxane is considered a palliative treatment for a variety of squamous cell carcinomas, Hodgkin's disease, non-Hodgkin's lymphoma, and testicular cancer.<sup>1</sup> Generic bleomycin sulfate was first approved on June 3, 1996.<sup>2</sup> The typical dose range is 0.25 to 0.50 units/kg (10 to 20 units/m<sup>2</sup>) weekly or twice weekly.<sup>3</sup>

**Cytoxin**

Cytoxin (cyclophosphamide) was originally approved on November 16, 1959, as an injectable and tablet therapy. The first generic of the injection formulation was approved in July 1986.<sup>4</sup> Generic tablets were first approved in August of 1999 and launched in 2000.<sup>5</sup> Cytoxin is often used in the treatment of breast cancer and non-Hodgkin's lymphoma, typically in combination with other oncolytics.<sup>6</sup> Oral Cytoxin dosing is usually in the range of 1 to 5 mg/kg per day, and intravenous regimens range from 3 to 5 mg/kg twice a week.<sup>7</sup>

**Paraplatin**

Paraplatin (carboplatin) was approved in March 1989, as a second-generation platinum-based compound, following the success of Platinol (cisplatin), BMS's first-generation,

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<sup>1</sup> "Blenoxane Inj, Monograph - Bleomycin Sulfate," Medscape Drug Reference, <http://www.medscape.com/druginfo/monograph?cid=med&drugid=6227&drugname=Blenoxane+Inj&monotype=monograph>.

<sup>2</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>.

<sup>3</sup> Blenoxane Product Label, April 1999.

<sup>4</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>.

<sup>5</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>; "Roxane Laboratories Inc. Introduces First Generic Cyclophosphamide Tablets," PR Newswire, April 13, 2000.

<sup>6</sup> "Cytoxin IV, Monograph – Cyclophosphamide," Medscape Drug Reference, <http://www.medscape.com/druginfo/monograph?cid=med&drugid=52888&drugname=Cytoxin+IV&monotype=monograph>.

<sup>7</sup> Cytoxin Product Label, Revised, November 2003.

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platinum-based compound approved in December 1978.<sup>8</sup> Paraplatin is typically used in the treatment of non-small-cell lung cancer (NSCLC), small-cell lung cancer (SCLC), and ovarian cancer.<sup>9</sup> The recommended dosage is a 300 mg/m<sup>2</sup> or 600 mg/m<sup>2</sup> infusion once every four weeks.<sup>10</sup> Paraplatin became subject to generic competition in 2004.<sup>11</sup>

### **Taxol**

Taxol (paclitaxel) was approved on December 29, 1992, as the first of the taxanes. It became subject to generic competition in 2000.<sup>12</sup> Taxol is used alone or in combination with other products, most often for the treatment of breast cancer, NSCLC, and ovarian cancer.<sup>13</sup> The recommended dosage of Taxol ranges from 135 to 175 mg/m<sup>2</sup>, typically administered every three weeks.<sup>14</sup>

### **VePesid**

VePesid (etoposide) in injectable form was launched in 1983, and became subject to generic competition in February 1994.<sup>15</sup> VePesid capsules were launched in 1987<sup>16</sup>; generics were first approved in September 2001.<sup>17</sup> VePesid is primarily used in combination with other agents for the treatment of testicular cancer and SCLC.<sup>18</sup> For

<sup>8</sup> “Bristol-Myers announces FDA approval of new anti-cancer drug,” PR Newswire, March 9, 1989; <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm>.

<sup>9</sup> “Paraplatin-IV, Monograph – Carboplatin,” Medscape Drug Reference, <http://www.medscape.com/druginfo/monograph?cid=med&drugid=4551&drugname=Carboplatin+IV&monotype=monograph>.

<sup>10</sup> <http://www.accessdata.fda.gov/scripts/cder/onctools/labels.cfm?GN=carboplatin>.

<sup>11</sup> Gray, Sally, “New business strategy,” Med Ad News, September 2004.

<sup>12</sup> Pena, Elisabeth, “Bristol-Myers Squibb Co.: No. 6,” Med Ad News, September 2001.

<sup>13</sup> “Taxol IV,” Medscape Drug Reference, <http://www.medscape.com/druginfo/monograph?cid=med&drugid=4685&drugname=Taxol+IV&monotype=monograph>.

<sup>14</sup> Taxol Product Label, 6/20/2000, pp. 39-40.

<sup>15</sup> BMSAWP/0011214–235 at 216.

<sup>16</sup> BMSAWP/0011214–235 at 216.

<sup>17</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>.

<sup>18</sup> “Etoposide IV,” Medscape Drug Reference, <http://www.medscape.com/druginfo/monograph?cid=med&drugid=8541&drugname=Etoposide+IV&monotype=monograph>.

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testicular cancer, the typical dose ranges from 50 to 100 mg/m<sup>2</sup> per day over five days. For small cell lung cancer, the range is 35 to 50 mg/m<sup>2</sup> per day over five days.<sup>19</sup>

**II. PRIMARY CARE/VIROLOGY PRODUCTS**

**Avapro**

Avapro (irbesartan) is an angiotensin II receptor (AT<sub>1</sub> subtype) antagonist/blocker (ARB).<sup>20</sup> It is indicated for the treatment of hypertension (alone or in combination with other therapies), with a secondary indication for diabetic nephropathy.<sup>21</sup> Avapro is available in 75, 150 and 300 mg tablets, with a recommended initial dose of 150 mg daily, and a maximum dose of 300 mg daily.<sup>22</sup>

Co-developed by BMS and Sanofi-Sythelabo<sup>23</sup>, Avapro was first approved for the treatment of hypertension on September 30, 1997. Approval for treatment of diabetic nephropathy was granted five years later on September 17, 2002.<sup>24</sup> No generic versions of irbesartan have been approved in the U.S. at this time.

Avapro competes directly with other ARBs, including Merck's Cozaar (losartan) and Novartis' Diovan (valsartan), the two largest selling ARBs in the U.S.

**BuSpar**

BuSpar (buspirone hydrochloride, USP) is an antianxiety agent that is indicated for the management of Generalized Anxiety Disorder.<sup>25</sup> BuSpar is available in 5, 10, 15, and 30 tablets with a recommended initial dose of 15 mg daily (7.5 mg 2 times a day), and a maximum daily dosage of 60 mg per day.<sup>26</sup>

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<sup>19</sup> VePesid Product Label, April 1999.

<sup>20</sup> Avapro Product Label, 3/16/2006, p. 3.

<sup>21</sup> Avapro Product Label, 3/16/2006, p. 11.

<sup>22</sup> Avapro Product Label, 3/16/2006, pp. 18–19.

<sup>23</sup> <http://newsroom.bms.com/index.php?s=ideas>

<sup>24</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

<sup>25</sup> BuSpar Product Label, 5/3/2001, pp. 1 and 3.

<sup>26</sup> BuSpar Product Label, 5/3/2001, p. 14.

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BuSpar tablets were approved on September 29, 1986, and capsules were approved on December 20, 2000, but have since been discontinued. Mylan and Watson Labs received approval for the first generic buspirone hydrochloride on March 28, 2001. An additional 10 generic forms of buspirone have since been approved by the FDA.<sup>27</sup>

**Cefzil**

Cefzil (cefprozil) is a semi-synthetic broad-spectrum cephalosporin antibiotic.<sup>28</sup> Cefzil is indicated for the treatment of patients with mild to moderate infections of the upper and lower respiratory track as well as skin and skin structure, caused by susceptible strains of designated microorganisms.<sup>29</sup> Cefzil is available in both tablet form and oral suspension. The tablets come in 250 and 500mg strengths, and the Oral Suspension is available in the 125/5ml and 250mg/5ml strengths. A typical course of therapy is ten days.<sup>30</sup>

Cefzil Tablets and Oral Suspension were both approved on December 23, 1991. Generics tablets first gained approval soon after patent expiration on November 14, 2005. Generic forms of the suspension were approved one month later.<sup>31</sup>

Cefzil faces competition from alternative cephalosporins such as Roche's injectable Rocephin and GSK's Zinnat/Ceftin.<sup>32</sup>

**Coumadin**

Coumadin (crystalline warfarin sodium) is an anticoagulant, or blood thinner, which acts by inhibiting vitamin K-dependent coagulation factors.<sup>33</sup> Coumadin is indicated for the prophylaxis and treatment of venous thrombosis, pulmonary embolism, thromboembolic complications associated with atrial fibrillation and cardiac valve replacement, and to reduce the risk of death from or recurrence of myocardial infarction and stroke.<sup>34</sup>

<sup>27</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>.

<sup>28</sup> Cefzil Product Label, 6/23/2004, p. 1.

<sup>29</sup> Cefzil Product Label, 6/23/2004, pp. 8–9.

<sup>30</sup> Cefzil Product Label, 6/23/2004, pp. 16–18.

<sup>31</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>.

<sup>32</sup> “Global Pharmaceuticals,” Deutsche Bank, 8/5/2005, pp. 177.

<sup>33</sup> Coumadin Product Label, 9/2/2005, p. 1.

<sup>34</sup> Coumadin Product Label, 9/2/2005, p. 8.

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Available both in tablets between 1 to 10 mg and as a lyophilized powder for injection, the Coumadin dosing is individualized for patients according to symptoms and patient response.<sup>35</sup>

First approved on June 8, 1954, Coumadin has given way to a number of generic and branded generic forms of warfarin sodium, the first wave of which, were subsequently discontinued. The first generic warfarin sodium to remain on the market was approved on March 26, 1997 and launched by Barr in July of that year. Other generic approvals followed: Sandoz (September 1997), Taro (July 1999), and Genpharm (September 2004) have since launched generic warfarin products.<sup>36</sup>

Coumadin competes with other anticoagulation agents. Heparin products are the principal therapeutic substitute for Coumadin and other warfarin products.<sup>37</sup>

**Glucophage**

Glucophage (metformin hydrochloride tablets) and Glucophage XR (metformin hydrochloride extended-release tablets) are both oral antihyperglycemic drugs used in the management of type II diabetes.<sup>38</sup> Both diabetes therapies fall into the biguanide class. In conjunction with diet and exercise, Glucophage and Glucophage XR are indicated for improvement of glycemic control in patients suffering from type II diabetes.<sup>39</sup>

Glucophage is available in 500, 850, and 1000 mg tablets, and Glucophage XR is available in 500 and 750 mg tablets.<sup>40</sup>

Glucophage was first approved on March 3, 1995 for improvement of glycemic control. It later received approval for a secondary indication for use with sulfonylurea or insulin products on October 22, 1998. Many generic versions of both metformin hydrochloride and extended-release metformin hydrochloride have been approved and brought to market. The first generic metformin hydrochloride products were approved on January

<sup>35</sup> Coumadin Product Label, 9/2/2005, pp. 2 and 23.

<sup>36</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>.

<sup>37</sup> “Global Pharmaceuticals,” Deutsche Bank, 8/5/2005, p. 281.

<sup>38</sup> Glucophage XR Product Label, 4/11/2003, p. 3.

<sup>39</sup> Glucophage XR Product Label, 4/11/2003, p. 17.

<sup>40</sup> Glucophage XR Product Label, 4/11/2003, pp. 31 and 32.

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24, 2002 and were introduced by Mylan, Goldline, Watson Labs, and Zenith Goldline. A generic extended-release was first approved on December 1, 2003.<sup>41</sup>

Glucophage and Glucophage XR mainly compete with other classes of type II diabetes treatments such as sulphonylureas, glitazones, secretagogues and alpha-glucosidase inhibitors.<sup>42</sup>

### **Glucovance**

Glucovance (glyburide and metformin hydrochloride tablets) is a combination of two oral antihyperglycemic drugs, glyburide and metformin HCL, used in the management of type II diabetes.<sup>43</sup> Glucovance was first indicated as an initial therapy for improving glycemic control in patients with type II diabetes. A secondary indication was later approved for use of Glucovance as a second-line therapy in combination with thiazolidinedione when initial treatment with a sulfonylurea or metformin was deemed inadequate.<sup>44</sup> Glucovance is available in three different tablet forms: 1.25 mg/250 mg, 2.5 mg/500 mg and 5 mg/500 mg.<sup>45</sup>

Glucovance was first approved as an initial type II diabetes therapy on July 31, 2000. The secondary indication for use in combination with a thiazolidinedione was approved on September 30, 2002. There are currently four generic versions of glyburide-metformin HCL available. Ivax Pharmaceuticals was the first to receive approval on February 18, 2004.<sup>46</sup>

Glucovance mainly competes with other classes of type II diabetes treatments such as sulphonylureas, glitazones, secretagogues and alpha-glucosidase inhibitors.<sup>47</sup>

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<sup>41</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

<sup>42</sup> “Global Pharmaceuticals,” Deutsche Bank, 8/5/2005, p. 104.

<sup>43</sup> Glucovance Product Label, 3/15/2004, p. 3.

<sup>44</sup> Glucovance Product Label, 3/15/2004. p. 13.

<sup>45</sup> Glucovance Product Label, 3/15/2004. p. 29.

<sup>46</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

<sup>47</sup> “Global Pharmaceuticals,” Deutsche Bank, 8/5/2005, p. 104.

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**Monopril**

Monopril (fosinopril sodium) is an angiotensin converting enzyme (ACE) inhibitor. Monopril is indicated as a primary treatment for hypertension and as an adjunctive therapy for heart failure.<sup>48</sup> This product is available in 10, 20 and, 40 mg tablets. The recommended starting dose is 10 mg once daily, with dosing adjusted between 20 to 40 mg daily depending on the response of the patient's blood pressure.<sup>49</sup> Monopril-HCT (fosinopril sodium with hydrochlorothiazide) is available in 10, 12.5, and 20 mg tablets.<sup>50</sup>

Monopril was first approved on May 16, 1991. A new indication was added on May 2, 1995, presumably for the treatment of heart failure.<sup>51</sup> Monopril-HCT was approved on November 30, 1994.<sup>52</sup> Teva launched the first generic fosinopril sodium product, which was approved on November 25, 2003. Andrx Pharmaceuticals received approval for the first generic HCT on December 3, 2004. Additional generic formulations of each have since been approved.<sup>53</sup>

There are numerous ACE inhibitors on the market that compete with Monopril.

Delix/Tritace/Altace (Sanofi-Aventis and King), Vasotec (Merck) and Accupril (Pfizer) are the leading ACE inhibitors.<sup>54</sup> There also exist alternative therapies for hypertension that compete against Monopril and other ACE inhibitors. These alternatives include ARBs, Beta Blockers, and Calcium Antagonists.<sup>55</sup>

**Plavix**

Plavix (clopidogrel bisulfate) is an inhibitor of ADP-induced platelet aggregation, commonly known as an anti-thrombotic agent. Plavix is indicated for use as an anti-

<sup>48</sup> Monopril Product Label, 5/27/2003, p. 7.

<sup>49</sup> Monopril Product Label, 5/27/2003, p. 21.

<sup>50</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>; No product label for Monopril-HCT was available on the Drugs@FDA website.

<sup>51</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

<sup>52</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

<sup>53</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

<sup>54</sup> "Global Pharmaceuticals," Deutsche Bank, 8/5/2005, p. 112.

<sup>55</sup> "Global Pharmaceuticals," Deutsche Bank, 8/5/2005, p. 110.

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thrombotic agent in patients who experience myocardial infarction, stroke or peripheral arterial disease, with a secondary indication for Acute Coronary Syndrome.<sup>56</sup> Plavix is available in 75 mg tablets, with a recommended initial loading dose of 300 mg to be followed by 75 mg daily.<sup>57</sup>

Plavix was co-developed by Sanofi-Sythelabo and BMS<sup>58</sup>, and was first approved on November 17, 1997.<sup>59</sup> The indication for Acute Coronary Symptom was approved on February 27, 2002.<sup>60</sup> The first generic version of clopidogrel bisulfate was developed by Apotex and approved on January 20, 2006.<sup>61</sup> There are currently no other generic forms available.

There are three different sub-segments within the anti-thrombotic category: anti-platelet aggregation agents, blood coagulation agents or heparins, and fibrinolytic agents. Plavix competes both with other anti-aggregation agents and drugs in the other two anti-thrombic classes, which include Reopro (Lilly) and Integritilin (Schering-Plough and GSK).<sup>62</sup>

**Serzone**

Serzone (nefazodone hydrochloride) is indicated for the treatment of depression. Serzone has a double mechanism of action that blocks the reuptake of 5-HT and antagonizes 5-HT2 putting the drug into the Serotonin Noradrenaline Reuptake Inhibitor (SNRI) class of anti-depressants.<sup>63</sup> Serzone is available in tablet form with a recommended starting dose of 200mg/day. The effective dose range is generally between 300 to 600 mg/day.

Serzone tablets were approved on December 22, 1994. The patent expired in March of 2003, and there are currently eight generic versions available. Generics from Dr. Reddy's

<sup>56</sup> Plavix Product Label, 10/14/2005, p. 15.

<sup>57</sup> Plavix Product Label, 10/14/2005, p. 23.

<sup>58</sup> <http://newsroom.bms.com/index.php?s=ideas>

<sup>59</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

<sup>60</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

<sup>61</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

<sup>62</sup> "Global Pharmaceuticals," Deutsche Bank, 8/5/2005, p. 121.

<sup>63</sup> "From mania to depression," ABN AMRO, 8/8/2003, p. 38.

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Labs, Ivax, Mylan, Ranbaxy, Roxane, Sandoz, Teva and Watson Labs were approved on September 16, 2003.<sup>64</sup>

The anti-depressant category includes three other classes, tricyclic antidepressants, monoamine oxidase inhibitors (MAOIs), and selective serotonin reuptake inhibitors (SSRIs), in addition to SNRIs.<sup>65</sup> SSRIs are the most widely prescribed anti-depressant drug therapy. The leading SNRI is Effexor (Wyeth).<sup>66</sup>

**Tequin**

Tequin (gatifloxacin) is indicated for the treatment of infections due to susceptible strains of bacteria that cause pneumonia, bronchitis, sinus and respiratory tract infections, urinary tract infections, and certain sexually transmitted diseases.<sup>67</sup> Tequin belongs to the quinolone class of antibiotics. At present, Tequin has been discontinued by BMS.<sup>68</sup> It was available in tablet, injection, and oral suspension form. The recommended daily dose ranged between 200 mg to 400 mg. A typical course of therapy was between 7 to 10 days.<sup>69</sup>

Tequin tablets, Tequin injections and Tequin (in 5% dextrose) injection were approved on December 17, 1999. An additional oral suspension form of Tequin was approved on August 27, 2004.<sup>70</sup> The patent on Tequin expires on December 25, 2007.

Tequin faced competition both within the quinolone class and the antibiotic category as a whole. In addition to quinolones, the main antibiotic classes consist of penicillins, cephalosporins, and macrolides. Levaquin (Johnson & Johnson) and Ciprofloxacin (Bayer) are the leading quinolones in the market.<sup>71</sup>

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<sup>64</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

<sup>65</sup> “Global Pharmaceuticals,” Deutsche Bank, 8/5/2005, pp. 209–210.

<sup>66</sup> “Global Pharmaceuticals,” Deutsche Bank, 8/5/2005, p. 210.

<sup>67</sup> “Pipeline Report,” Life Science Analytics, 12/19/2006, p. 136.

<sup>68</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

<sup>69</sup> Tequin Product Label, 12/17/1999, p. 16.

<sup>70</sup> <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>

<sup>71</sup> “Global Pharmaceuticals,” Deutsche Bank, 8/5/2005, pp. 177-179.